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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,353	07/23/2001	Mark Dehdashtian	VAS-5644	3388

7590 09/23/2004

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EXAMINER	
JACKSON, ANDRE K	

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,353	DEHDASHTIAN ET AL.	
	Examiner	Art Unit	
	André K. Jackson	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1,4-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dancu et al. (WO0232224).

Regarding claim 1, Vilendrer discloses a "High frequency intravascular prosthesis fatigue tester" which has pre-tester with fixtures to couple the free ends of the tissue tube, a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. Vilendrer does not disclose an animal tissue tube. However, Dancu et al. disclose in "System and method to simulate hemodynamics" which uses an animal tissue tube (Abstract, Pages 11,23, 26). Therefore, to modify Vilendrer to include an animal tissue tube as taught by Dancu et al. would have been obvious to one of ordinary skill in the art at the time of the invention. By adding animal tissue the user would be able to simulate hemodynamic patterns of physiological blood flow of the human vascular system.

Regarding claim 4, Vilendrer discloses a pulsatile pumping system for fluid supply that pressurizes the tissue tube lumen to pressures found in the human vascular system (Column 6, 46-54).

Regarding claim 5, Vilendrer discloses a sensor for measuring the exterior diameter of the tissue tube (Column 6, lines 30-45).

Regarding claim 6, Vilendrer discloses where the sensor is non-contact sensor (Column 3, line 64).

Regarding claim 7, Vilendrer discloses where sensor is a laser micrometer (Column 4, line 9).

Regarding claim 9, Vilendrer discloses where sealingly coupling opposed free ends of a tissue tube onto fixtures of a pre-tester (Figure 3), positioning a stent within the tissue tube (Figure 6, column 4, line 35) and providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36), a fluid supply in communication with at least one of the fixtures (Figure 6) and a stent. Vilendrer does not disclose an animal tissue tube. However, Dancu et al. disclose an animal tissue tube (Abstract, Pages 11,23, 26). Therefore, to modify Vilendrer to include an animal tissue tube as taught by Dancu et al. would have been obvious to one of ordinary skill in the art at the time of the invention. By adding animal tissue the user would be able to simulate hemodynamic patterns of physiological blood flow of the human vascular system.

Regarding claim 10, Vilendrer discloses pressurizing the fluid in the tissue tube lumen to pulsatile pressures found in the human vascular system (Column 2, 5-9).

Regarding claim 11, Vilendrer discloses measuring the exterior diameter of the tissue tube at different pressures (Column 6, line 54).

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dancu et al. as applied to claim 1 above, and further in view of Bier et al.

Regarding claim 2, neither Vilendrer nor Dancu et al. disclose where the animal tissue is porcine. However, Bier et al. discloses animal tissue that is swine, which is porcine. Therefore, since it is known to use animal tissue for testing as evidenced by Dancu et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include where the animal tissue is porcine since the tissue is close to human tissue.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer in view of Dancu et al. and Bier et al. as applied to claim 2 above, and further in view of Love et al.

Regarding claim 3, neither Vilendrer nor Dancu et al. disclose where the animal tissue is a section of porcine aorta with any side branches ligated. However, Love et al. discloses where the animal tissue is a section of porcine (Column 1, lines 33-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify Vilendrer to include where the animal tissue is a

section of porcine as taught by Bier et al. since tissue is in close characteristics to human tissue. Side branches are not disclosed but it would be within the purview of the skilled artisan to ligate the branches to prevent the any leakage.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dancu et al. as applied to claim 1 above, and further in view of Glenn et al.

Regarding claim 8, neither Vilendrer nor Dancu et al. disclose where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the animal tissue tube at the axially spaced locations. However, Glenn et al. disclose where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the tube at the axially spaced locations (Page 1, Introduction and page 2 Test methods). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include where the stented graft has multiple individual wires at axially spaced locations along the outer graft tube and where the sensor is positioned to measure the exterior diameter of the animal tissue tube at the axially spaced locations as taught by Glenn et al. since this modification would provide an exact measurement of the diameter of the tube's diameter.

6. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilendrer (5670708) in view of Dancu et al. as applied to claim 9 above, and further in view of Glenn et al. (EnduraTec.com/papers/nitenol).

Regarding claim 12, Vilendrer discloses: recording data (12) on the measured exterior diameter of the tissue tube; sealingly coupling opposed free ends of a tissue tube onto fixtures of a tester (Figure 3); positioning a stent within the tissue tube (Figure 6, column 4, line 35); providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36); pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54); and measuring the exterior diameter of the synthetic tube and controlling the fluid pressure based on the recorded data (Column 6, lines 4-19). Neither Vilendrer nor Dancu et al. disclose a pre-tester. However, Glenn et al. discloses an "Accelerated pulsatile fatigue testing on NI-TI coronary stents" which uses a pre-tester (Page 2, Test Methods). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include a pre-tester as taught by Glenn et al. since this would help in compliance testing.

Regarding claim 13, neither Vilendrer nor Dancu et al. disclose where the fluid pressure in the synthetic tube is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube. However, Glenn et al. does disclose where the fluid pressure in the synthetic tube is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior

diameter of the animal tissue tube (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer by using fluid pressure in the synthetic tube which is controlled to expand the diameter of the synthetic tube to the same dimension as the measured diameter of the exterior diameter of the animal tissue tube as taught by Glenn et al. since this would mimic the action of human arteries.

Regarding claim 14, Vilendrer discloses where the tube lumen is pressurized to both normal and abnormal pulsatile pressures found in the human vascular system and the synthetic tube lumen is pressurized at a pulsed rate based on the measured exterior diameter of the tissue tube to simulate both normal and abnormal compliance conditions (Column 6).

Regarding claim 15, neither Vilendrer nor Dancu et al. disclose pressurizing the fluid in the tube lumen to pulsatile pressures found in the human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures. However, Glenn et al. disclose pressurizing the fluid in the tube lumen to pulsatile pressures found in the human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vilendrer to include pressurizing the fluid in the tube lumen to pulsatile pressures found in the human vascular system and measuring the exterior diameter of the tube at the axially spaced locations and at different pressures as taught by Glenn

et al. since this modification would give the tube an exact measurement of the diameter of the tube and mimic the action of human arteries.

Regarding claim 16, Vilendrer discloses: recording data (12) on the measured exterior diameter of the tissue tube; sealingly coupling opposed free ends of an tissue tube onto fixtures of a tester (Figure 3); positioning a stent within the tissue tube (Figure 6, column 4, line 35); providing a fluid to the tissue tube lumen via at least one of the fixtures (Column 4, line 36); and pressurizing the fluid in the tube lumen at a pulsed rate (Column 6, lines 45-54). Neither Vilendrer nor Dancu et al. disclose measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations. However, Glenn et al. disclose measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters of the synthetic tube at axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations (Page 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vilendrer to include measuring the exterior diameter of the synthetic tube at the axially spaced locations while controlling the fluid pressure based on the recorded data such that the diameters

of the synthetic tube at axially spaced locations expands to the same dimensions as the measured diameter of the exterior diameter of the animal tissue tube at axially spaced locations as taught by Glenn et al. since this modification would provide an exact measurement of the diameter of the tube and mimic the action of human arteries.

Response to Arguments

7. Applicant's arguments filed 06/24/04 have been fully considered but they are not persuasive. Applicants have argued that neither Vilendrer nor Dancu disclose the use of animal tissue for testing and that the Examiner should look to the instant application for the distinction between "animal" and "human". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner has taken the broadest interpretation of "animal". Dancu uses human or mammalian veins for testing. According to Merriam Webster's Collegiate Dictionary tenth edition mammals are considered animals. Dancu teaches that testing is done on both synthetic (prior art) and on saphenous veins. This modification of animal tissue would allow the user to be able to simulate hemodynamic patterns of physiological blood flow of the human vascular system.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to André K. Jackson whose telephone number is (571) 272-2196. The examiner can normally be reached on Mon.-Thurs. 7AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.J.

September 17, 2004

DANIEL S. LARKIN
PRIMARY EXAMINER